K004001

OCT - 4 2001

510(k) SUMMARY

SUBMITTER:	Dideco S.p.A. 86, Via Statale 12 Nord 41037 Mirandola (MO) Italy
CONTACT PERSON:	Luigi Vecchi Phone: 011 39 0535 29811 Fax: 011 39 0535 25229
DATE PREPARED:	Noveber 2, 2000
DEVICE TRADE NAME:	Monolyth Phospholypidic Inert Surface In Oxygenation (Mimesys) Adult Hollow Fiber Oxygenator
COMMON NAME:	Hollow Fiber Oxyenator/Reservoir
CLASSIFICATION NAME:	Cardiopulmonary Bypass Oxygenator
PREDICATE DEVICES:	Monolyth (k922933/A) Lilliput Ph.I.S.I.O. (K991737)

DEVICE DESCRIPTION:

The Monolyth Mimesys is a hollow filber membrane oxygenator with an integral heat exchanger and an attached hardshell venous reservoir The blood contact surfaces of the oxygenator have been coated with a phosphorilcholine coating. The coating provides a uniform biocompatible surface.

INDICATION FOR USE:

The Monolyth Mimesys is intended for use in adults who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation. The device provides oxygenation and removal of carbon dioxide from venous or suctioned blood. The integral heat exchanger provides blood temperature control, allows for the use of hypothermia, or aids in the maintenance of normothermia during surgery. The integral reservoir is intended for use as a storage reservoir (gravity or vacuum-assisted) for venous return blood and/or as a filtered cardiotomy reservoir for intrathoracic suctioned blood in an extracorporeal circuit. Following intraoperative use, the reservoir is used for the collection and autotransfusion of shed blood and/or chest drainage. The Monolyth Mimesys has been tested for 6 hours of continuous use; use longer than 6 hours is not advised.

TECHNOLOGICAL CHARACTERISTICS:

The Monolyth Mimesys membrane oxygenator is identical in design to the Monolyth membrane oxygenator. In addition, all blood contact surfaces have been coated with a biocompatible phosphorilcholine coating. The coating is identical to the PC coating used on the D901 Lilliput Ph.I.S..O. The oxygenator is ethylene oxide sterilized and has a nonpyrogenic fluid path. It is for single use only.

BIOCOMPATIBILITY TEST RESULTS:

A complete battery of tests were carried out in accordance with the requirements of ISO 10993-1:1992 and the FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing on the raw materials. The whole coated device aged up to two years (accelerated ageing) was tested for Hemolysis, Cytotoxicity, Irritation, Acute Systemic Toxicity and Mutagenicity. Sterility, pyrogenicity, ETO residuals and package integrity tested were also conducted. The results of this testing met established specificaitons.

IN VITRO TEST RESULTS

Product performance testing included gas transfer studies, pressure drop, plasma-leakage data, operaing blood volumes, heat exchanger performance evaluation, hemolysis/cell depletion study, mechanical integrity, venous/cardiotomy reservoir characterization and leachables/flaking study. Test protocols used were based on the draft guidance. "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submission" issued on January 17, 2000 by CDRH and, whwew applicable, upon the ISO 7199 (1996) standard for Cardiovascular Implants and Artificial Organs - Extra Corporeal Blood-Gas Exchangers.
All tests were performed upon aged devices (accelerated ageing up to 2 years); for comparative purposes, the same testing (when applicable) was conducted also on the Monolyth predicate device.
The results of this testings show that the device is comparable to the predicate devices for all characteristics.

CONCLUSIONS

The results of in vitro mass transfer studies demonstrate that the Monolyth Mimesys oxygenator performs in a manner substantially equivalent to the predicate device. Biocompatibility studies demonstrate that the phosphorilcholine coating is biocompatible and functional testing demonstrate that its performances are equivalent to the predicate device. Additional testing has also demonstrated the effectiveness of production techniques to assure that the device is sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 4 2001

Ms. Barbara Watson
DIDECO
c/o COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, CO 80004-3599

Re: K004001
Trade Name: Monolyth Mimesys Hollow Fiber Oxygenator
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary bypass oxygenator.
Regulatory Class: II
Product Code: DTZ
Dated: July 6, 2001
Received: July 10, 2001

Dear Ms. Watson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K004001

Device Name: Monolyth integrated membrane lung with Mimesys coating

Indications For Use:

The Monolyth Hollow Fiber Oxygenator is intended for use in adults who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation. It provides oxygenation and carbon dioxide removal from venous blood. The integrated heat exchanger provides blood temperature control and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The venous reservoir with cardiotomy filter is intended for use as a storage reservoir (gravity or vacuum-assisted) for venous return blood and/or as a filtered cardiotomy reservoir for intrathoracic suctioned blood in an extracorporeal circuit to assure the proper oxygenation capability of the device. Following intraoperative use, the reservoir is used for the collection and autotransfusion of shed blood and/or chest drainage. The Monolyth integrated membrane lung with Mimesys coating is intended to be used for six hours or less.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K004001

Prescription Use _____ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

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